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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,246	02/08/2000	Todd P. Foster	6231.N-CN1	2305

7590 09/29/2006

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/500,246	FOSTER ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/4/2005, 7/19/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-28,32,33,36-38 and 42-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-28,32,33,36-38 and 42-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/4/2005 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-28,32,33,36-38,42-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cady et al. (US Pat. 6,498,153) in view of Okada et al. (US Pat. 4,652,441), Babcock et al. (US Pat. 3,417,182), Montgomery et al., Grimm (US Pat. 5,522,797) and Remington's Pharmaceutical Sciences (17th Ed. 1985).

Cady et al. discloses first composition containing growth promoters, such as estradiol and/or trenbolone and a second composition containing said growth promoters and biodegradable polymer, each of said first and second compositions may contain starch, ethylcellulose, cellulose acetate, sucrose and polyvinylpyrrolidone (Columns 1-4). It is disclosed that the first composition is prepared by process comprising operations conventional in the pharmaceutical arts, for example the mixture of ingredients is granulated, screened and tableted into pellets (Column 7, lines 62-68, Column 8, lines 1,2). The second composition is formulated

by mixing the ingredients, forming granulates, screening and tableting the granulate (Column 8, lines 3-11). It is disclosed that the compositions are administered parenterally, typically, subcutaneously as pellets to an inedible member of the animal, such as a cow; by means of a syringe or pellet gun (Column 9, lines 13-25, Column 10, lines 5-17). It is disclosed that the uncoated pellets releases the growth promoter immediately whereas release of the coated pellet is delayed providing sustained release Column 7, lines 20-32, Column 9, lines 1-23).

Okada et al. discloses that disintegrating agents include starch (Column 9, lines 19-27).

Babcock et al. teach that melengesterol acetate is injectable and implantable and useful in the veterinary field for control of estrual periods and stimulation of growth (See entire document, especially Abstract, Column 1, lines 41-45).

Montgomery et al. disclose that melengesterol acetate, trenbolone acetate and estradiol can be used together and that anabolic implants have been used as a production tool by cattle feeders for several decades (See entire reference, especially pages 1 and 4).

Grimm discloses a veterinary implanter for injecting a plurality of pellet doses, including approved growth hormones, into the hide, skin or ears of an animal, such as cattle (Column 1, lines 5-14, 60-68, Column 4, lines 1-45). It is disclosed that the implanter avoids the problems of prior art implanters, failing to leave the pellets in the ear when withdrawing the needle or forgetting to advance the pellet magazine, by automatically advancing the pellet magazine and ejecting the pellets from the needle (Columns 1, 2).

Remington's discloses that small particles go into solution faster than large particles and that if a pharmacist wishes to increase the rate of solution of a drug he should decrease the size (Pg. 208). It is disclosed that the more soluble the solute the faster the rate of solution (Pg. 208).

It is disclosed that freeze-dried product are often more soluble and/or more rapidly soluble (Pg. 1538). It is disclosed that micronizing is one method of particle size reduction (Pg. 1585).

The prior art discloses the combination of immediately and sustained release pellets for implantation of steroids. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an implant composition consisting essentially of a first component comprising pellets of melengestrol acetate with disintegrating agent capable of immediately releasing the melengesterol and a second component comprising pellets of melengestrol acetate not containing a disintegrating agent which is capable of releasing on a sustained basis said melengestrol suitable for administration by a single injection consisting essentially of one to four pellets of the first component and four to six pellets of type the second component and a method of delivering an implant containing the first claimed component and the second claimed component by injecting the implant into the animal body. However, the prior art amply suggests the same as the prior art discloses implants containing hormones such as melengestrol acetate, trenbolone acetate and estradiol for increasing growth in animals, that said hormones can be used together and that hormone implants, such as pellets, can be injected into animals, and implants with and without disintegrating agents, in the form of tablets or pellets, containing polymers, waxes, oils, fats or fatty acid esters, and that a plurality of implants may be administered, and implants containing a first component in containing melengestrol acetate and disintegrating agent in a tablet for immediate release and melengestrol acetate without a disintegrating agent in a tablet for sustained release. Also, the prior art discloses that small particles go into solution faster than larger particles, that micronizing is one method of reducing particle size, that the more soluble the solute is the faster the rate of solution and that freeze

drying often results in a more soluble and/or more rapidly soluble product. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art with the expectation of increasing the growth of animals by injecting a plurality of devices as an implant into the body of the animal, such as in the ear, which avoids a slow start up time by use of an immediately releasing component in combination with a sustained releasing component. Further, it would have been well within the skill of to modify the particles in the immediately releasing pellet by reducing their size and/or freeze drying with the expectation that immediate releasing characteristic of the said pellet would be enhanced and to use larger sizes of particles in the slow releasing pellet with the expectation that that slow releasing characteristics of said pellet would be enhanced.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 26-28,32,33,36-38,42-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung et al. (US 2002/01105998) in view of Cady et al. (US Pat. 6,498,153), Okada et al. (US Pat. 4,652,441), Babcock et al. (US Pat. 3,417,182), Montgomery et al., Grimm (US Pat. 5,522,797) and Remington's Pharmaceutical Sciences (17th Ed. 1985).

Chung et al. disclose the administration to an animal of an implant which contains an immediate-release formulation containing an anabolic agent and a controlled-release formulation containing an anabolic agent with a controlled-release agent, where the combination acts to stimulate growth and weight gain (Paragraph 0016). It is disclosed that the formulation can be in the form of compressed tablets or pellets and include such anabolic agents as estradiol and

trenbolone acetate (Paragraphs 0018- 0021). It is disclosed that the immediate-release formulation can be used with diluents, excipients, tableting agents, such as lactose, magnesium stearate, silica and starches (Paragraph 0022). It is disclosed that the controlled-release agent can be a polymer matrix such as biodegradable and non-biodegradable polymers and that the same can be combined with diluents, excipients, tabletting agents, including lactose, magnesium stearate and silica (Paragraph 0023).

Cady et al. (US Pat. 6,498,153), Okada et al. (US Pat. 4,652,441), Babcock et al. (US Pat. 3,417,182), Montgomery et al., Grimm (US Pat. 5,522,797) and Remington's Pharmaceutical Sciences (17th Ed. 1985) are cited for the same reasons as above and are incorporated herein to avoid repetition.

The prior art discloses the combination of immediately and sustained release pellets for implantation of steroids. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an implant composition consisting essentially of a first component comprising pellets of melengestrol acetate with disintegrating agent capable of immediately releasing the melengesterol and a second component comprising pellets of melengestrol acetate not containing a disintegrating agent which is capable of releasing on a sustained basis said melengestrol suitable for administration by a single injection consisting essentially of one to four pellets of the first component and four to six pellets of type the second component and a method of delivering an implant containing the first claimed component and the second claimed component by injecting the implant into the animal body. However, the prior art amply suggests the same as the prior art discloses implants containing hormones such as melengestrol acetate, trenbolone acetate and estradiol for increasing growth in animals, that said

hormones can be used together and that hormone implants, such as pellets, can be injected into animals, and implants with and without disintegrating agents, in the form of tablets or pellets, containing polymers, waxes, oils, fats or fatty acid esters, and that a plurality of implants may be administered, and implants containing a first component in containing melengestrol acetate and disintegrating agent in a tablet for immediate release and melengestrol acetate without a disintegrating agent in a tablet for sustained release. Also, the prior art discloses that small particles go into solution faster than larger particles, that micronizing is one method of reducing particle size, that the more soluble the solute is the faster the rate of solution and that freeze drying often results in a more soluble and/or more rapidly soluble product. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art with the expectation of increasing the growth of animals by injecting a plurality of devices as an implant into the body of the animal, such as in the ear, which avoids a slow start up time by use of an immediately releasing component in combination with a sustained releasing component. Further, it would have been well within the skill of to modify the particles in the immediately releasing pellet by reducing their size and/or freeze drying with the expectation that immediate releasing characteristic of the said pellet would be enhanced and to use larger sizes of particles in the slow releasing pellet with the expectation that that slow releasing characteristics of said pellet would be enhanced.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/21/06

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